REMARKS

Claims 1 and 3 have been amended. New Claim 21 has been added. No new matter has been introduced. Reconsideration is respectfully requested in view of the above amendments and following remarks.

Applicants' Response to 35 U.S.C. § 112, Second Paragraph Rejection

Claim 1 stands rejected under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse the rejection.

The Examiner contends that there is insufficient antecedent basis for the term "said tubular structure" in Claim 1. Applicants have amended Claim 1 to read "said tubular extrudate" rather than "said tubular structure," per the Examiner's suggestion.

Accordingly, Applicants submit that, in light of the above, the rejection of Claim 1 under 35 U.S.C. § 112, second paragraph, has been overcome and should be withdrawn.

Applicants' Response to 35 U.S.C. § 102 Rejection over Zilla

Claims 1 and 3 are rejected under 35 U.S.C. § 102(e), as allegedly being anticipated by WO 00/30564 to Zilla, et al. (hereinafter "Zilla"). Applicants respectfully traverse the rejection on the basis that Zilla fails to disclose, teach, or suggest each and every limitation of Applicants' amended claims.

The Examiner contends that Zilla discloses a medical device or vascular graft comprising a tubular extrudate of a PTFE matrix having domains of an extractable polymeric material. The Examiner further contends that Zilla discloses exposing the extrudate to a dissolving medium or

degrading temperature to extract a portion of the polymer, forming pores.

Zilla discloses a vascular prosthesis including a structure having an inner-connected helically oriented channel with a porosity to allow oriented in-growth of connective tissue into a wall of the prosthesis. The graft material comprising the vascular prosthesis in Zilla is polyurethane. Polytetrafluoroethylene is not used as the graft material, but rather may be used in a limited capacity as a "non-extractable fiber." *See* Zilla, page 5, lines 9-20.

According to Zilla, the most preferred method for producing the graft is a fiber winding technique. Zilla discloses, however, melt extrusion as an alternative technique, according to which:

> a molten graft material containing chopped strands of extractable fibers is extruded from an extrusion die specially adapted to orient fibrous fillers in an extrudate.
> (Zilla, page 11, lines 2-4).

The molten graft material of Zilla requires thermoplastic elastomers, preferably polyurethanes. The graft material may contain additional, non-extractable fibers for reinforcement. Such fibers may include non-elastic, non-degradable materials such as PTFE. Nowhere in Zilla, however, is a graft material containing an interpenetrating polymer network disclosed, taught, or suggested.

In contrast, Applicants' amended claims are directed to a tubular extrudate, which includes an interpenetrating polymer network ("IPN"). The IPN is a network of PTFE and another polymer, such as, for example, silicones. The polymer may be extracted from the IPN in accordance with the disclosure of the present application to leave behind a porous PTFE structure. Support for this recitation is found on pages 15-16 of the present application, as originally filed. Additional support for such IPN networks may be found in U.S. Patent No. 6,022,092, which is incorporated by reference in the present application, as originally filed.

Zilla fails to disclose, teach, or suggest an interpenetrating network including PTFE and another extractable polymeric component. As such, Zilla fails to disclose, teach, or suggest each and every limitation of Applicants' amended claims.

It is well settled that to be an effective anticipatory reference, a cited document must disclose each and every limitation recited in a claim under examination. Failing such precise disclosure, such a cited document must fail as an anticipatory reference.

Accordingly, Applicants submit that, in light of the above, the rejection of Claims 1 and 3 under 35 U.S.C. § 102(e) based on Zilla has been overcome and should be withdrawn.

Applicants' Response to 35 U.S.C. § 103 Rejection over Zilla in view of Dereume

Claim 2 is rejected under 35 U.S.C. § 103(a), as allegedly being obvious over Zilla in view of U.S. Patent No. 5,639,278 to Dereume et al. (hereinafter "Dereume"). Applicants respectfully traverse the rejection on the basis that the Examiner has failed to establish a prima facie case of obviousness.

In addressing Zilla as a §102 reference, Applicants have already described in detail that Zilla does not provide nor even suggest a medical device having an interpenetrating polymer network including a PTFE matrix. For the sake of brevity, Applicants will not repeat the discussion on Zilla.

For the same reasons that Zilla fails as a reference under 35 U.S.C. §102, the combination of Zilla and Dereume fail as a proper combination under 35 U.S.C. §103. Dereume is cited only for its teachings of combining a stent and a graft together and fails to teach or suggest anything of any relevance to the present invention as recited in the amended claims. Dereume clearly fails to cure the deficiencies of Zilla. The combination of Zilla and Dereume therefore fails to disclose each and every element of the claimed invention.

Withdrawal and reconsideration of the rejection is therefore respectfully requested.

In view of the foregoing, Claims 1-3 and 21 are now believed to be in proper form for allowance. A favorable reconsideration of the application on the merits is earnestly solicited.

If the Examiner has any questions regarding this Response, she is encouraged to contact the undersigned attorney.

Respectfully submitted,

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VERSION OF AMENDMENT WITH MARKING SHOWING CHANGES MADE

IN THE SPECIFICATION:

Please replace paragraph [0019] on page 6 with the following paragraph:

[0019] In another aspect of the invention there is provided a method of forming a porous PTFE product which includes the steps of: providing a mixture of PTFE resin and an extractable polymer material; extruding said mixture to form an extrudate which includes a PTFE matrix with discrete domains of said extractable polymer material; subjecting said extrudate to a solvent for said extractable polymer material, a temperature sufficient to grade said extractable polymer material or a combination thereof, whereby at least a portion of said extractable polymer material is extracted, thereby forming pores in said extrudate.

IN THE CLAIMS:

1. (Amended) A medical device comprising:

a tubular extrudate comprising an interpenetrating polymer network comprising a PTFE matrix having distributed therein discrete domains of an extractable polymeric material, wherein upon exposure to sufficient dissolving medium or degradation temperature, said discrete domains are extracted from said matrix to create pores in said tubular extrudate ~~structure~~.

3. (Amended) A vascular graft comprising:

a tubular extrudate comprising an interpenetrating polymer network comprising a PTFE matrix having distributed therein discrete domains of an extractable polymeric material, wherein upon exposure to sufficient dissolving medium or degradation temperature, said discrete domains are extracted from said matrix to create pores in said tubular extrudate.

21. (New) The medical device according to Claim 1, wherein said extractable polymeric material comprises silicone.